REMARKS

Applicants have further amended claims 1 and 40 to more particularly define the invention taking into consideration the outstanding Official Action and the telephone conversation with Examiner Hoffmann. The outstanding official action urges that applicants RCE and amended claims represents a shift in the claimed invention from a method of making a foamed ceramic to a method of altering a human or animal body. The undersigned attorney noted that there was no such intention and that the same invention was being prosecuted as had been previously examined. The amendments were made in response to the Examiner's rejection.

In any case, it is believed that it has been agreed with the Examiner that the present further amendment, removing step e), will obviating any holding that there has been a shift in the claimed invention. Accordingly, it is most respectfully requested that the reply be considered as it is fully responsive to the outstanding rejection.

Currently amended claim 40 is a combination of amended claim 1 and claim 3. Claim 3 has been canceled as redundant. The amendments to the claims are fully supported by the specification as originally filed. Applicants most respectfully submit that all of the claims now present in the application, claims 1, 2, 4 -27 and 31-40, are in full compliance with 35 USC 112 and are clearly patentable over the references of record.

Applicants have amended claim 1 to explicitly state that the ceramic material is biocompatible. These limitations are supported by the specification as originally filed as would be interpreted by one of ordinary skill in the art to which the invention pertains. In this regard, the reference to 40,000 hip replacements on page one of the specification would be clearly understood to refer to human patients. The reference to the various known implants on page 2 further supports the intended use and the meaning of biocompatible as would be interpreted by one of ordinary skill in the art to

which the invention pertains. It is most respectfully submitted this amendment overcomes the Examiner's comments that the "intended use is very broad" (see the paragraph bridging pages 3 and 4 of the last Office Action). The terms must be given a reasonable interpretation as would be understood by one of ordinary skill in the art to which the invention pertains.

With regard to the Examiner's comment that the present application does not describe the actual use of the material in-vivo, Applicants submit herewith a copy of a scientific paper by the inventor (Karin Hing et al), which is entitled "Microporosity enhances bioactivity of synthetic bone graft substitutes", Journal of Materials Science: Materials in Medicine 16 (2005) 467-475. It can be seen that this scientific paper specifically refers to the method according to the present invention (see page 468, bottom of first column, and the References, Refs. 17 and 18). The paper presents some positive in-vivo results. As would be appreciated by one of ordinary skill in the art, at the time of the filing of the present application, the material may be used in vivo. The paper describes the actual use of the material in-vivo. The specification as originally filed refers to such a specific use on page 3. It is stated at lines 24-27, that the present invention aims to provide a method for the manufacture of porous material with highly interconnected porosity, which are suitable for use in medical applications.

Moreover, the paper supports Applicants statement that using a ball mill to foam the synthetic bone material enables the independent control of the level of total porosity and the level of strut porosity. Clearly, this paper does support Applicants submission that there is a new/unexpected effect associated with using a ball mill to foam biomedical ceramic materials for use in the human or animal body.

Applicants believe that the important point to stress is that only the present invention has appreciated the advantages associated with ball milling foam-stabilized slips in the production of macroporous ceramic synthetic bone materials for biomedical applications. These advantages are described in the present application (see pages

8, 9, 12 and 21 of the specification) and also in the attached scientific paper. These include:

(i) no organic sponge/foam template or solid pore-formers to burnout; porous ceramics produced by burnout methods often have relatively low mechanical properties resulting from defects in the structure due to incomplete/irregular burnout of the original template;

(ii) homogeneous or functionally graduated pore distributions are attainable by varying the slip viscosity;

(iii) macro-pore size is variable by varying the start-powder particle size;

(iv) macro-porosity is highly interconnected; and

(v) the microstructure contains an interconnected network of micro-pores, the degree of connectivity of which can be controlled during sintering. These advantages enable control of the pore structure so as to minimize batch variation and the production of substantially isotropic open structures. The claimed processing route therefore enables the structural features, such as the pore size and connectivity, of both the macro-porosity and micro-porosity of the biomedical ceramic material to be tailored to the specific application so that structural and mechanical properties may be matched to particular requirements for use in the human or animal body.

The present application already provides evidence of the technical advantages associated with using a ball mill to foam the synthetic bone material for biomedical applications (see the Examples and the Figures). In particular, the scanning electron micrographs of the biomedical ceramics presented in the Figures show that using a ball mill to foam the synthetic bone material enables the independent control of the level of total porosity and the level of strut porosity. This may be contrasted with the prior art foaming methods for biomedical applications, which do not achieve this level of control. In this regard, Applicants attach an information sheet which provides examples of the

prior art foaming methods (e.g. blending, shaking, blowing gas, and gas nucleation) and the typical microstructures of the materials so produced.

With regard to the macroporosity aspect of the microstructure, the conventional method of blending/beating can be seen to result in uni-directional fragmentation of large cells leading to an ellipsoidal pore geometry, which can inhibit the ingress of mesenchymal cells and blood vessels in vivo. The conventional method of shaking can result in multi-directional fragmentation of large cells leading to wide pore size distribution and lower interconnection size, which again can inhibit the ingress of mesenchymal cells and blood vessels in vivo. In the conventional method of blowing gas through a slurry, the pore size is determined by slurry viscosity, nozzle diameter and flow rate. It is often difficult to control pore size distribution due to foam coarsening. The conventional method of gas nucleation can result in a non-uniform and non-interconnected microstructure due to pore coarsening caused by the partial pressure of the blowing agent. Finally, in the conventional method of phase burn-out, entrapment of carbon can occur in closed pores, and expansion of the sacrificial phase on burn-out often leads to scaffold micro-fracturing.

In view of the foregoing, the present inventors have found that the conventional foaming methods for preparing biomedical ceramics all have their drawbacks. Moreover, the present inventors have found unexpectedly that the application of a ball mill to foam the ceramic slip results in the controlled development of a mono-modal distribution of well interconnected spherical pores and the independent control of the level of total porosity and the level of strut porosity. The present inventors have found that the resulting microstructure results in a synthetic biomedical ceramic having improved properties when used in the human or animal body.

New claim 40 is based on a combination of currently amended claim 1 and dependent claim 3, which recites that the milling media have a diameter in the range of from 10 to 30 mm (and from 15 to 25 mm in claim 34). These ranges are not

disclosed in US 5,895,897. While US 5,656,562 does mention 13 mm milling media, this is for grinding the starting powder, not for foaming a ceramic slip. Similarly, while US 5,395,722 does mention 1-30 mm milling media, this is for grinding an organic perylene pigment, not for foaming a ceramic slip. There is no teaching or suggestion in any of the documents that such sized milling media could or should be relied on in the formation of a ceramic foam, let alone a ceramic foam for a synthetic bone material for use in the human or animal body, where the pores have a modal diameter d(mode) of at least 100 microns.

Additionally, on page 8 of the present specification Applicants state that it is preferable that the amount of ceramic particulate when mill-foaming the ceramic slip is from 3 to 20 w/w% ceramic particulate to the milling media (more preferably from 5 to 15 w/w% ceramic particulate to the milling media). This feature is not taught by WO 93/04013, US 5,895,897 or US 5,656,562. While US 5,395,722 does refer to using 1 to 20 parts by weight milling media to 1 part by weight (organic perylene) pigment (see columns 5, line 68 -Column 6, line 1), Applicants most respectfully submit that this is not relevant to the present case. This is because US 5,395,722 does not use a ball mill to create a ceramic foam. The mill is simply used to grind an organic perylene pigment.

There is also a difference in that the perylene pigment in US 5,395,722 is milled in the absence of any liquid carrier. Thus, it is not appropriate to rely on the disclosed range of 1 to 20 parts by weight milling media to 1 part by weight (organic perylene) pigment because our proposed range would refer to the weight of the ceramic particulate when provided in a liquid carrier. In any case, it would be necessary to combine three separate and completely unrelated documents (i.e. WO 93/04013, US 5,895,897 and US 5,395,722) to even come close to this feature in combination with the features of claim as claimed in claim 40. Moreover, there is absolutely no motivation in the prior art for such a combination. Thus, the combination of references does not render the claimed subject matter prima facie obvious to one of ordinary skill in the art

to which the invention pertains. Moreover the resulting properties of the biocompatible material of the present invention are clearly shown as discussed above and the additional publication submitted herewith.

The statement on page 3 of the Final rejection that, "A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art" is specifically traversed. It is the differences in the process of making which results in the difference in properties of the product which results in the patentability of the claimed process. The specific processing steps of the presently claimed invention distinguishes the claimed invention over the prior art.

The decisions cited by the Examiner in support of the Examiner's holding have been carefully considered but it is most respectfully submitted that they do not support the argument presented. Whether a preamble of intended purpose constitutes a limitation to the claims is, as has long been established, a matter to be determined on the facts of each case in view of the claimed invention as a whole. In re Duva, 387 F.2d 402, 407, 156 USPQ 90, 94 (CCPA 1967); In re Walles, 366 F.2d 786, 790,151 USPQ 185,190 (CCPA 1966). The test in determining whether a claimed invention would have been obvious is what the combined teachings of the references would have suggested to one of ordinary skill in the art. In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 198 1). In the present case, the claimed invention is not prima facie obvious for the reasons already of record, herein incorporated by reference and the additional amendments to the claims and information submitted herewith.

The rejection of claims 1, 4 -27, 32,3 and 35-39 under 35 U.S.C. 103(a) as being unpatentable over WO 93/04013 in view of Oishi et al. has been carefully considered but is most respectfully traversed in view of the amendments to the claims and the following comments.

At the outset, Applicants wish to direct the Examiner's attention to the basic requirements of a prima facie case of obviousness as set forth in the MPEP § 2143. This section states that to establish a prima facie case of obviousness, three basic criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Section 2143.03 states that all claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Applicants most respectfully submit that a prima facie case of obviousness of the presently claimed subject matter has not be established as it is submitted that it would not have been obvious to modify the process described in WO 93/04013 in view of the disclosure of US 5,895,897.

Amended claim 1 is directed to A method of producing a synthetic bone material for use in biomedical applications, said synthetic bone material comprising a macroporous ceramic foam which has an open foam structure containing pores and having an open foam structure containing pores with a modal diameter $d_{mode} \geq 100$ µm.... Thus, the claimed method is concerned with making a synthetic bone material

for biomedical applications (see page 1, lines 1 to 5 of Applicants' specification). As now amended, claim 1 specifies that the ceramic particulate is biocompatible.
The term "macroporous" means an open foam structure containing pores with a modal diameter $d_{mode} \geq 100$ µm (see the text on page 4, lines 14 to 17). Claim 1 also now specifies that the synthetic bone material is used in the human or animal body as set forth in step (e) of the method. This obviates the Examiner's comments on page three of the Official Action that the claims do not appear to require using the material as an implant. The claims now also require a use step. These are claim limitations which cannot be ignored.

Claim 1 is further limited in that the step of foaming the ceramic slip in step (b) is carried out using a ball mill.

Claim 1 is novel over WO 93/04013 for at least the reason that this prior art document does not disclose the step of foaming a ceramic slip using a ball mill (step (b)). It is clear that WO 93/04013 achieves foaming by the injection of gas into the dispersion. Claim 1 is further distinguished from WO 93/04013 in that the claimed method is directed to a method of producing a macroporous ceramic foam for use in biomedical applications and having an open foam structure containing pores with a modal diameter $d_{mode} \geq 100$ µm.

Accordingly, claim 1 differs from WO 93/04013 by virtue of at least the feature of foaming the ceramic slip using a ball mill and also in that the ceramic foam is a macroporous ceramic foam for use in biomedical applications having an open foam structure containing pores with a modal diameter $d_{mode} \geq 100$ µm.

It is further noted that the method according to the primary reference does not appear to result in a porous foamed ceramic structure that would be suitable for use as a biomedical material (e.g. a bone graft substitute) as required by the claims now present in the application. For this purpose, the foamed macroporous ceramic material must exhibit open porosity, as opposed to closed porosity, and must have a modal pore

size ≥100 µm. This is clearly discussed in the description of the present application (see pages 4 and 5) and reflected by the wording of claim 1. Indeed, the reference to the Buchner funnel in Examples II, III and IV of the primary reference would be expected by one of ordinary skill in the art to result in pores having a similar size to that of the filter, i.e. 10 to 16 µm.

Example VIII teaches a slip of hydroxyapatite wherein the product had a mean pore diameter of 24 µm. Moreover, the primary reference states that the pores may be closed and/or the porosity may be open at page 11, second full paragraph. There is no positive teaching in the primary reference of the open pore structure which is a claim limitation of all of the claims now present in the application. Applicants' specification may not be used as a teaching reference.

Applicants note that the primary reference does refer to gas entrapment by mechanical means and suggests that this may be achieved simply by stirring. This is exemplified in Examples V-X, where a paddle stirrer or stirring in a beaker was used. The other Examples (Example I-IV) rely on a Buchner funnel to produce the foam. It is therefore clear that one of ordinary skill in the art would appreciate that the primary reference had identified what it considered to be suitable methods for forming a foamed ceramic. There is no indication in the primary reference that there were any problems associated with these foaming methods. Accordingly, there simply would not be any motivation for a person skilled in the art to look elsewhere for an alternative foaming technique.

Claim 1 is further limited in that the step of foaming the ceramic slip in step (b) is carried out using a ball mill. The importance of the properties of the synthetic bone material achieved by ball milling in accordance with the claims on appeal is described in Applicants' specification and is not suggested in the prior art relied upon in the rejection. As discussed on pages 8, 9 and 21 of Applicants' specification, there are a

number of advantages associated with ball milling foam-stabilised slips formed in accordance with the presently claimed invention including:

(I) No organic sponge/foam template or solid pore-formers to burnout; porous ceramics produced by burnout methods often have relatively low mechanical properties resulting from defects in the structure due to incomplete/irregular burnout of the original template;

(ii) Homogeneous or functionally graduated pore distributions are attainable by varying the slip viscosity;

(iii) Macro-pore size is variable by varying the start-powder particle size; (iv) Macro-porosity is highly interconnected; and

(iv) Microstructure contains an interconnected network of micro-pores, the degree of connectivity of which can be controlled during sintering. This is important for tailoring the drug delivery characteristics of the porous structure.

These advantages enable control of the pore structure so as to minimize batch variation and the production of substantially isotropic open structures. The claimed processing route therefore enables the structural features, such as the pore size and connectivity, of both the macro-porosity and micro-porosity to be tailored to the specific application so that structural and mechanical properties may be matched to particular requirements. It is pointed out that all the Examples featured in the present application rely on the use of a ball mill to achieve foaming of the ceramic slip. Thus, the use of a ball mill is a specific aspect of the invention and not simply an equivalent method of foaming the slip.

As noted on page 6 of Applicants' specification the organic binder serves to provide plasticity during forming of the ceramic particulate and green strength in the formed product. It is also noted that all of the examples in Applicants' specification include an organic binder. At page 7, line 5, of Applicants' specification, it is stated that the organic binder will generally be present in a liquid carrier in an amount of from 0.2

to 10 w/v% and more preferably from 0.5 to 6 w/v%. The specific and preferred limitations are specifically set forth in claims 12, 13 and 35 on appeal. There is absolutely no suggestion in the prior art of these specific ranges which are claim limitations. The necessary motivation is not in the prior art to suggest these preferred aspects of the presently claimed invention and for this reason, these claims are further distinguished over the prior art.

The only disclosure in the primary reference to the use of a binder is at page 9 which simply suggests that binders such as resins may be included but there is no suggestion of the specified amounts which are clearly indicated to be preferred embodiments of the presently claimed invention. The examples in the primary reference do not use binders let alone suggest the amounts specified in claims 12, 13 and 35. While the '897 patent describes the use of an organic binder in the paragraph beginning at column 3, line 25, this relates to a foam slurry which is produced by mixing an alumina based ceramic powder, SiC whiskers, and a solution containing a dispersant, an organic binder and a foaming agent in water. This in no way suggests a modification of the primary reference to arrive at the presently claimed preferred binder concentrations as claimed in claims 11, 12 and 35 on appeal.

As discussed at page 20 of Applicants' specification, the results in Table 3 and Figures 7-10 demonstrate how variation in the ratio of ceramic particulate to binder solution variation in both the bulk density (macro-porosity) and the strut density (micro-porosity). The sintered mill-foamed porous ceramics prepared with the greater volume of liquid carrier have lower bulk and strut densities reflecting a more open, inter-connected pore structure with large macro-pores and a larger fraction of micro-porosity.

As noted at page 21, the macro-porous ceramic foams according to the present invention have advantages over the prior art cancellous and coral derived materials. The sintered ceramic foam has a bulk porosity in the range of from 70 to 90% as specifically claimed in claim 37 and a slightly broader range in claim 25. These are

specific claim limitations which again are in no way suggested by the prior art. The strut density is specified in claims 26 and 38. Clearly, these limitations are present in the claims, discussed in the specification, and further distinguish the claimed subject matter over the prior art.

Claim 1 differs from the teachings of the primary reference for at least the reasons that this prior art reference does not disclose that the foamed macroporous ceramic material must exhibit open porosity, as opposed to closed porosity, and must have a modal pore size $\geq$100 µm and the step of foaming a ceramic slip using a ball mill (step (b)). It is clear that the primary reference achieves foaming by the injection of gas into the dispersion by either mechanical means e.g. stirring or using a filter of defined pore size, see page five, first paragraph of the primary reference.

In an effort to overcome one of the deficiencies of the primary reference, the Final Rejection relies on the teachings of the '897 patent for foaming by ball milling. However, the '897 patent is directed to a light-weight ceramic acoustic absorber for use in the exhaust nozzles of a jet engine. This reference is directed to a light-weight ceramic acoustic absorber for use in the exhaust nozzles of a jet engine. It is, accordingly, clear that US 5,895,897 lies in a completely different technical field from that of the present invention, i.e. synthetic bone materials for biomedical applications.

Applicants most respectfully submit that the skilled person, seeking to improve the properties of a ceramic foam for biomedical applications, would not modify the disclosure of WO 93/04013 based on the teaching of US 5,895,897. This absorber has a dense layer provided on the surface of the foamed ceramic, including ceramic fibers as stated at column 2, lines 55-57 which is distinctly different from the structure formed by the process of the present invention as would be appreciated by one of ordinary skill in the art. It is, accordingly, clear that '897 lies in a completely different technical field from that of the present invention, i.e. synthetic bone materials for biomedical applications. Applicants most respectfully submit that the skilled person, seeking to

improve the properties of a ceramic foam for biomedical applications, would not modify the disclosure of the primary reference based on the teaching of the '897 patent related to forming an acoustic absorber to obtain the presently claimed invention. In particular, there is no suggestion in either the primary reference or the '897 patent that the use of a ball mill to achieve foaming of a ceramic slip would result in an improved biomedical ceramic material. Accordingly, there would be no motivation for the skilled person to combine the teachings of the primary reference with the '897 patent, absent Applicants' teaching. In re Fritch, 23 USPQ 1780, 1784(Fed Cir. 1992) ("It is impermissible to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps.). Moreover, obvious to try is not the standard of obviousness under 35 USC 103(a).

It is further noted that the method according to WO 93/04013 does not appear to result in a porous foamed ceramic structure that would be suitable for use as a biomedical material (e.g. a bone graft substitute) as contemplated by the present application. For this purpose, the foamed macroporous ceramic material must exhibit open porosity, as opposed to closed porosity, and must have a modal pore size $\geq$100 µm. This is clearly discussed in the description of the present application (see pages 4 and 5) and reflected by the wording of claim 1. Indeed, the reference to the Buchner funnel in Examples 2, 3 and 4 of WO 93/04013 would be expected to result in pores having a similar size to that of the filter, i.e. 10 to 16 µm.

As already stated, document US 5,895,897 does not disclose a method of producing a synthetic bone material for use in biomedical applications, e.g. for use as a bone graft substitute. There is also no indication that the ceramic according to US 5,895,897 has an open macroporous structure with a modal pore size $\geq$ 100 µm, as required by claim 1 of the present application.

Thus, there would be no motivation for one skilled in the art to combine documents WO 93/04013 and US 5,895,897. There is no indication in either documents that ball milling could or should be used to achieve the required macroporous open foam structure, which is necessary for certain biomedical applications. Indeed this feature is clearly precluded by document WO 93/04013.

As stated in MPEP section 2143, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990) (Claims were directed to an apparatus for producing an aerated cementitious composition by drawing air into the cementitious composition by driving the output pump at a capacity greater than the feed rate. The prior art reference taught that the feed means can be run at a variable speed, however the court found that this does not require that the output pump be run at the claimed speed so that air is drawn into the mixing chamber and is entrained in the ingredients during operation. Although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." 916 F.2d at 682, 16 USPQ2d at 1432.).

Even in the unlikely event that the documents were combined, neither document teaches or suggests that foamed macroporous ceramic material has open porosity (as opposed to closed porosity) with a modal pore size $\geq$ 100 μm. Thus, the combination of references cannot render the claims prima facie obvious.

As discussed in the present application on pages 8, 9 and 21, there are a number of advantages associated with ball milling foam-stabilized slips, including:

(i) No organic sponge/foam template or solid pore-formers to burnout; porous ceramics produced by burnout methods often have relatively low mechanical properties resulting from defects in the structure due to incomplete/irregular burnout of the original template;

(ii) Homogeneous or functionally graduated pore distributions are attainable by varying the slip viscosity;

(iii) Macro-pore size is variable by varying the start-powder particle size; (iv) Macro-porosity is highly interconnected; and

(iv) Microstructure contains an interconnected network of micro-pores, the degree of connectivity of which can be controlled during sintering. This is important for tailoring the drug delivery characteristics of the porous structure.

These advantages enable control of the pore structure so as to minimize batch variation and the production of substantially isotropic open structures. The claimed processing route therefore enables the structural features, such as the pore size and connectivity, of both the macro-porosity and micro-porosity to be tailored to the specific application so that structural and mechanical properties may be matched to particular requirements. It is pointed out that all the Examples featured in the present application rely on the use of a ball mill to achieve foaming of the ceramic slip. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 2 and 3 under 35 U.S.C. §103(a) as being unpatentable over WO 93/04013 in view of Oishi et al, as applied to claims 1 and 4-27, 32, 33 and 35-39 above, and further in view of WU has been carefully considered but is most respectfully traversed.

US 5,656,562 relates to a method of improving the properties of ceramic green bodies. While US 5,656,562 does mention the use of a ball mill, this is not used to prepare a foamed ceramic. Instead, the ball mill is merely used to prepare (i.e. mill) the starting powders. This is clear from column 5, lines 31 to 42, were, the powders are milled and then separated from the grinding media. Only then is a slurry formed by adding deionized water. Thus, US 5,656,562 merely describes the conventional technique of using grinding media to mill starting powders. US 5,656,562 is not

concerned with foamed ceramics, nor synthetic bone materials for biomedical applications.

The rejection of claims 2 and 3 under 35 U.S.C. §103(a) as being unpatentable over the primary reference in view of the '897 patent as applied to claims 1, 4 -27, 32, 33 and 35-39 above, and further in view of Wu, the '562 patent, is also untenable and should be reversed for the reasons discussed above with respect to the combination of the primary reference and the '897 patent. The '562 patent does not overcome the deficiencies of the combination of references relied upon in the first obviousness rejection.

In the Final Rejection, the Examiner states that '562 patent is cited to teach a conventional size of grinding media. However, claim 2 on appeal is not concerned with milling powders using a grinding media. Instead, claim 2 is concerned with foaming a ceramic slip in a ball mill. This differs from the teaching of the '562 patent in that the starting material is a ceramic slip (not a starting powder) and in that the process produces a foam (not a milled powder). These are fundamental differences as would be appreciated by one of ordinary skill in the art to which the invention pertains. As the Examiner has acknowledged, the '562 patent is not concerned with foamed ceramics, nor synthetic bone materials for biomedical applications.

Applicants note that claim 40 defines that the milling media have a diameter in the range of from 10 to 30 mm. This range is not disclosed in the '897 patent. While the '562 patent does mention 13 mm milling media, this is for grinding the starting powder, not for foaming a ceramic slip. There is no teaching or suggestion in any of the documents that such sized milling media could or should be relied on in the formation of a ceramic foam in accordance with the requirement of claim 3, let alone a ceramic foam for a synthetic bone material, where the pores have a modal diameter as specified by the claims on appeal.

The '562 patent relates to a method of improving the properties of ceramic green bodies. While the '562 patent does mention the use of a ball mill, this is not used to prepare a foamed ceramic. Instead, the ball mill is merely used to prepare (i.e. mill) the starting powders. This is clear from column 5, lines 31 to 42, were, the powders are milled and then separated from the grinding media. Only then is a slurry formed by adding deionized water. Thus, the '562 patent merely describes the conventional technique of using grinding media to mill starting powders. The '562 patent is not concerned with foamed ceramics, nor synthetic bone materials for biomedical applications.

In view of the above comments, it is considered that the disclosure of the '562 patent has been taken out of context and does not establish a prima facie case of obviousness for the claimed subject matter and this rejection should be withdrawn in view of the above comments and further amendments to the claims.

The rejection of claims 2 , 3 and 34 under 35 U.S.C. §103(a) as being unpatentable over the primary reference in view of the '897 patent as applied to claims 1, 4-27, 32, 33 and 35-39, above, and further in view of Nukada et al US 5,395,722, the '722 patent, is also untenable and should be reversed for the reasons discussed above with respect to the combination of the primary reference and the '897 patent. The '722 patent does not overcome the deficiencies of the first obviousness rejection.

With regard to the '722 patent, this reference is even further removed relating as it does to a electrophotographic photoreceptor. Even though the '722 patent does mention the use of a ball mill, this is used to prepare (i.e. mill) an organic perylene pigment. The '722 patent has nothing to do with ceramic powders let alone the preparation of a foamed ceramic bone material for biomedical applications. This reference was located by looking for claimed limitations and then searching the prior art for these limitations. This is improper hindsight reconstruction of the prior art to arrive

at the claimed invention. Accordingly, it is most respectfully requested that this rejection be withdrawn.

Applicants believe that the present amendment places the application in condition for allowance. However, if this is not the case, Applicants wish to conduct an interview with the Examiner and would appreciate it very much if the Examiner would be so kind as to contact the undersigned attorney to arrange the interview.

In view of the above comments, further amendments to the claims, and addition documents submitted with the previous response, favorable reconsideration and allowance of all of the claims now present in the application are most respectfully requested.

Respectfully submitted,

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